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| EXAMINER | |
|---|---|
| PARA, ANNETTE H | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1661 | |

DATE MAILED: 09/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/052,771 | SCHILLINGER ET AL. | |
| | Examiner | Art Unit | |
| | Annette H. Para | 1661 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *01 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,2,4-10,13,25,33,35,39,42 and 43* is/are pending in the application.

4a) Of the above claim(s) *25, 33, 35, 39, 42, 43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 4-10, 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Byrum's declaration filed on June 1, 2004 has been fully considered but it is not persuasive.

Byrum declares that PAT enzyme is involved in the synthesis of amino acids in plant cells (declaration page 2, § 7). This statement is not found persuasive. Phosphinothricin acetylase, which confers glufosinate resistance, is not involved in plant metabolism, thus the gene encoding this enzyme cannot interfere with amino acids synthesis in plants. Byrum adds that soybean plants do not naturally exhibit herbicide tolerance and that the effect of transgene expression is unpredictable (declaration page 3). This is not found persuasive. Nontransgenic resistance to the herbicide glyphosate has been observed in soybean plants and many plants have been produced that are resistant to glyphosate or glufosinate herbicides. Then Byrum declares that the expression of an herbicide resistance transgene creates a "metabolic drag". This is not found persuasive. Applicant has cited any art showing that transforming a plant with EPSPS or PAT would create a metabolic drag. To make his point Byrum then cites several references. This not found persuasive. None of the references refer to transgenic plants, they are drawn to classical breeding and are all drawn to crossing plants with multi genes traits; crossing plants with two single gene traits is straight forward. Additionally the reference from Wilcox et al. shows that it is possible to cross soybean plants in order to transfer two traits that are each the result of numerous genes into the same plant. Also, crossing is not required to produce the instant plants, as transformation would suffice.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4-10, and 13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

> *An applicant shows possession of the claimed invention by describing the claimed invention with* ***all its limitations.*** *"* MPEP 2163. *"Possession may be shown in many ways. For example, possession may be shown by describing an actual reduction to practice of the claimed invention. Possession may also be shown by a clear depiction of the invention in detailed drawings or in structural chemical formulas which permit a person skilled in the art to clearly recognize that applicant had possession of the claimed invention."* MPEP 2163

"A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process." MPEP 2163. "The analysis of whether the specification complies with the written description requirement calls for the examiner to compare the scope of the claim with the scope of the description to determine whether applicant has demonstrated possession of the claimed invention....

The claims are drawn to transgenic or nontransgenic soybean seeds or plants comprising genes conferring resistance to at least the herbicides glyphosate and gluphosinate. The soybean seeds comprising said resistance are not described in the specification to demonstrate that the Applicants had possession of the claimed invention. Applicants have not deposited any seeds of the soybean because there is no Deposit Accession Number.

Further applicants have described the specific gene expressing glyphosate resistance by citing patent number 6,177,617 and the specific gene expressing gluphosinate resistance by citing patent number 5,710,368. Applicants do not describe the combination of glyphosate and gluphosinate resistance, nor do they describe, which gene sequence encoded protein would exhibit said resistance, other than those described by patent No. 6,177,617 and No. 5,710,368. For instance, the skilled artisan would not know what particular gene sequences would import said resistance without a clear elucidation of a core sequence that would encode said resistance polypeptide. Although *Information which is well known in the art need not be described in detail in the specification."* MPEP 2163, it is improper to cite references for essential subject matter.

More over the skilled artisan would not have recognized that applicants were in possession of any other nucleic acid sequences that would encode such polypeptides since the activity of any polypeptide is not only dependent on primary structure but secondary and tertiary structure as well. Without a core polypeptide sequence and a representative number of species the skilled artisan would not have envisioned any other polypeptide sequence having said activities.

Claims 1-10, and 13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of stacking 2 particular herbicide resistance genes (ie. glyphosate and sulfonylurea, or glufosinate and sulfonylurea), does not reasonably provide enablement for methods stacking more than 2 herbicide resistance genes, nor the stacking of any other combination of resistance genes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The specification is not enabling for methods stacking more than 2 herbicide resistant genes, as well as for stacking genes resistant specifically to glyphosate and gluphosinate for the reasons discussed in the rejection above.

Nature of the invention: The claims are drawn to a transgenic or nontransgenic seed, plant, pollen, ovule, and tissue culture comprising genes conferring resistance to at least the herbicides glyphosate and gluphosinate.

Scope of the invention: The claims are of very broad scope, drawn to any seed, plant, pollen, ovule, or tissue culture comprising any gene or genes conferring resistance to **at least** glyphosate and glufosinate herbicides.

Guidance in the specification: The specification describes prophetically a method of introducing genes conferring a level of resistance to glyphosate and gluphosinate (pages 16-17). The specification describe the development of soybean variety having a level of resistance to both glyphosate and sulfonylurea, or glyphosate + synchrony, or glufosinate + sulfonylurea herbicides but does not mention the development of specific soybean variety having a level of resistance to both glyphosate and gluphosinate. The specification does not teach the stacking of

two or more herbicide resistant genes in soybean plants or part of plants other than those described in the examples. The specification also does not teach any method of producing glufosinate resistant soybean plants other than by transformation. Thus, the specification teaches no soybean plants comprising nontransgenic glufosinate resistance.

Working examples in the specification: There is no working example in the specification, which disclose the stacking of more than 2 herbicide resistant genes. The working examples disclosed in the specification are limited to genes conferring resistance to two herbicides as discussed above, but not specifically for glyphosate and gluphosinate herbicides.

State of the prior art: No prior art teaches stacking more than two herbicide resistant genes in plant or neither part of plant nor specifically the stacking of glyphosate and gluphosinate resistance.

Predictability of the art: It is highly unpredictable. Dr. Joseph R. Byrum declares in Appendix 1, p.2 that *the expression of a herbicide resistance transgene requires manipulation of complex metabolic pathways of plant cells.* According to the Byrum declaration combining more than one herbicide resistance transgene is very difficult as many factors are involved such as pleitropic effects, synergetic effects, and negative correlation of certain traits (Appendix 1, p.3).

Amount of experimentation necessary: The specification provides working example for stacking 2 herbicide resistant genes, but no working examples for stacking genes resistant specifically to glyphosate and gluphosinate as well as stacking more than 2 herbicide resistant genes. It would require much experimentation for one skilled in the art to practice the claimed method in view of the Byrum declaration since the declaration clearly asserts that the skilled artisan could not predict the interactions of transgenes in plants. The skilled artisan would have to engage in undue trial and error experimentation to generate plants with resistance to both glufosinate and glyphosate herbicides since the simple transformation of plants with a known transgene sequence is not sufficient to predictably result in a multiply herbicide resistant plant as averred by Dr. Byrum in the declaration. Furthermore the skilled artisan would expect the generation of plants with more than two herbicides resistant genes to be exponentially more

difficult than the generation of dual herbicide resistance since one would expect an increased interaction at the transgene expression products as noted in the declaration.

Conclusion: Thus the disclosure does not contain sufficient evidence regarding the scope of subject matter claimed as to enable one skilled in the art to make and use the claimed invention commensurate with that claimed without undue experimentation. This is particularly true given the state of the prior art, the amount of experimentation necessary, the absence of guidance and working examples in the specification, and the unpredictable nature of the art.

**Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C.103(a) which forms the basis for all obviousness rejections set forth in this Office action:
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 4-10, and 13 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Padgette et al. in view of Songstad et al. and further in view of Krueger.

Padgette et al. teach soybean seeds and plants that have resistance to glyphosate via transformation with a gene from *Agrobacterium*.(page 1452) Padgette et al. also teach use of said resistant plant in crosses to produce hybrid soybean plants that are resistant to glyphosate (see page 1455).

Songstad et al. teach soybean plants that have resistance to glufosinate via transformation. (see claims 1, 3, 5, 15). It would have been obvious to take the soybean plants having glufosinate resistance of Songstad et al. and the soybean plants having glyphosate resistance of Padgette et al., and to cross them to produce a hybrid plant, using the methods of producing hybrids using each plant, as taught by Padgette One would have been motivated to do so, given the teaching of Krueger to do so.

Since different herbicides are effective against different weeds, one would have been motivated to produce soybeans resistant to multiple herbicides in order to increase the number of weeds, which, could be readily controlled in soybean fields. Reasonable expectation of success would have been expected knowing the achievement obtain by Padgette et al. Thus the claimed invention would have been prima facie obvious as a whole at the time it was made, especially in the absence of evidence to the contrary.

**Future Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette H. Para whose telephone number is (571) 272-0982. The Examiner can normally be reached Monday through Thursday from 5:30 am to 4:00 pm.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Andrew Wang, can be reached on (571) 272-0811. The fax numbers for the group is (703) 872-9306. The Technology Center phone number is (571) 272-1600. Any inquiry of a general nature or relating to the status of this application should be directed to the Matrix Customer Service Center whose telephone number is (703) 872-9305.

A.H.P

ANNE KUBELIK
PATENT EXAMINER